

REMARKS/ARGUMENTS

Claims 1-2, 5, and 7-15 have been amended. Support for these amendments can be found throughout the specification, and in the original claims, as described below. Therefore, no new matter has been added by way of claim amendment. Entry of these amendments into the above-identified application is respectfully requested.

The specification has been amended to correct the formatting of trademarked terms, to update priority information, and to make minor changes in format or correction of typographical or grammatical errors. Accordingly, support for these amendments may be found in the original specification.

Claim 1 has been amended to change the phrase "wherein the said peptide" to "wherein the peptide." Claims 2, 7-10, 14, and 15 have been amended to change the phrases "selected from" and "selected from the group" to "selected from the group consisting of." Claim 5 has been amended to change the phrase "A particle according claim 1" to "A particle according to claim 1." Claim 8 has been amended to correct the typographical error wherein "methotrexate" was misspelled as "methotrxate." Claim 10 has been amended to change the phrase "an hydrophilic substituent" to "a hydrophilic substituent." Claims 11-13 have been amended to change the phrase "amino acid identity" to "amino acid sequence identity." Claim 15 has been amended to add SEQ ID NOS corresponding to the recitation of peptides A-F. All of these claim amendments except for the insertion of SEQ ID NOS in claim 15 reflect minor changes in format or correction of typographical or grammatical errors. Accordingly, support for these amendments may be found in the original claims. Support for the amendment of claim 15 to insert SEQ ID NOS may be found in Figure 7.

Claims 1-15 are under examination in the application. Claims 16-25 are withdrawn from consideration as being drawn to a nonelected invention. Reexamination and reconsideration of claims 1-15 are respectfully requested in view of these amendments and the following remarks. The Examiner's comments in the Office Action are addressed below in the order set forth therein.

The Objection to the Specification Should Be Withdrawn

The Examiner has objected to the specification with respect to the formatting of trademarked terms, improper spacing for the phrase "10minutes" on page 25, and for referring to Application No. 09/269,533 in the priority information now that this application has issued as U.S. Patent No. 6,670,452. The Applicants have amended the specification to correct the formatting of trademarked terms, to amend

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the phrase "10minutes" to "10 minutes" on page 25, and to update the priority information on page 1. Accordingly, this objection should be withdrawn.

The Objection to the Declaration Should Be Withdrawn

The declaration is objected to as being defective. Applicants submit concurrently herewith a Supplemental Declaration in compliance with 37 C.F.R. §1.67(a) for entry into the record of this application. Accordingly, this objection should be withdrawn.

The Objection to the Claims Should Be Withdrawn

Claim 1 has been objected to for reciting the phrase "wherein the said peptide." The claim has been amended to recite "wherein the peptide." Accordingly, this objection should be withdrawn.

Claim 5 has been objected to for reciting the phrase "A particle according claim 1." Claim 5 has been amended to change the phrase "A particle according claim 1" to "A particle according to claim 1." Accordingly, this objection should be withdrawn.

Claim 8 has been objected to for the typographical error "methotrxate." Claim 8 has been amended to correct for this misspelling. Accordingly, this objection should be withdrawn.

Claim 10 has been objected to for reciting the phrase "an hydrophilic substituent." The Examiner suggests amending the claim to recite "a hydrophilic substituent." Applicants have amended claim 1 as suggested by the Examiner. Accordingly, this objection should be withdrawn.

The Rejection of the Claims Under 35 U.S.C. §112 Should Be Withdrawn

Claims 9, 11-13, and 15 have been rejected under 35 U.S.C. §112, second paragraph, on the grounds that they are indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. The rejection is respectfully traversed.

Claims 9 and 15 have been rejected on the basis that the phrase "selected from the group" is improper Markush claim language. Applicants have amended claims 2, 7-10, 14, and 15 to change the phrases "selected from" and "selected from the group" to "selected from the group consisting of." Accordingly this rejection should be withdrawn.

Claims 11-13 have been rejected for reciting the phrase "amino acid identity." Applicants have amended the claims as suggested by the Examiner to state "amino acid sequence identity." Accordingly this rejection should be withdrawn.

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Claim 15 has been rejected on the basis that peptides A-F are not defined in the claim. Applicants have amended claim 15 to insert SEQ ID NOS corresponding to peptides A-F. Accordingly this rejection should be withdrawn.

In view of the above arguments, all grounds for rejection under 35 U.S.C. §112, second paragraph, have been overcome. Reconsideration and withdrawal of the rejections are therefore respectfully requested.

The Rejection of the Claims Under 35 U.S.C. §102 (b) Should Be Withdrawn

Claims 1, 2, and 8-11 are rejected under 35 U.S.C. §102(b) as being anticipated by Lundberg *et al.* (1993) *Biochim. Biophys. Acta* 1149:305-12. This rejection is respectfully traversed.

The Examiner contends that Lundberg *et al.* teach a non-naturally occurring receptor competent LDL particle comprising a peptide component (apolipoprotein B) wherein the peptide component has a binding site for an Apo B protein receptor and a lipophilic substituent that contains cholesterol. The Examiner further states that the presence of hydroxyl, carboxyl, and amino groups is inherent in the amino acids that make up peptides. Finally, the Examiner states that since the peptide component of the particle is apolipoprotein B, it is inherent that the peptide has 100% amino acid identity to an Apo B protein binding sequence. For these reasons, the Examiner states that the limitations of claims 1, 2, and 8-11 have been met. Applicants respectfully disagree.

Claim 1 contains the limitation that the peptide component is bonded at the amino and/or carboxy terminus thereof to at least one lipophilic substituent. There is no disclosure in Lundberg *et al.* that the peptide component is bonded at the amino and/or carboxy terminus thereof to at least one lipophilic substituent. On the contrary, Lundberg *et al.* describes Apo B associated with and incorporated into the envelope layer of lipid molecules in micelles, as described below.

The procedure described in Lundberg *et al.* for joining apolipoprotein B with liposomes is detailed at page 306, right hand column. Specifically, a detergent solubilization procedure was used wherein the detergents were sodium cholate (NaC) and octyl glucoside (OG). The passage describes taking lipid components, mixing them with the detergents OG and NaC, drying, adding buffer, and sonicating. This procedure results in the solubilization of lipids and the formation of micelles. These micelles were then added to Apo B and the mixture was gently stirred until a clear solution was formed. The detergents were then removed and the solution became opaque, indicating the formation of liposomes.

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Using this procedure described in Lundberg *et al.*, Apo B becomes associated with and incorporated into the envelope layer of lipid molecules in the micelles. This would not, and does not, cause Apo B to become bonded at the amino and/or carboxy terminus thereof to the lipid components. The Lundberg *et al.* liposomes are therefore not equivalent to a lipoprotein particle as described in claim 1 (from which claims 2-15 depend).

Because the Lundberg *et al.* reference does not disclose a peptide component bonded at the amino and/or carboxy terminus thereof to at least one lipophilic substituent, this cited reference does not meet all of the limitations of any of the pending claims in the present application. To anticipate a claim, a reference must teach every element of the claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Accordingly, Applicants respectfully request that the rejection of claims 1, 2, and 8-11 under 35 U.S.C. §102(b) be withdrawn.

Double-Patenting Rejection

The Examiner has rejected claims 1-15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,670,452. Applicants file concurrently herewith a terminal disclaimer in compliance with 37 C.F.R. §1.321(c) disclaiming any patent term beyond the term of U.S. Patent No. 6,670,452. Accordingly, Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

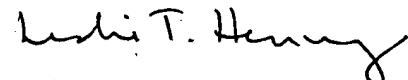
In view of the aforementioned amendments and remarks, Applicants respectfully submit that the objections to the specification and claims have been obviated, and the rejections of the claims under 35 U.S.C. §§ 112, second paragraph, and 102(b) are overcome. Accordingly, Applicants submit that this application is now in condition for allowance. Early notice to this effect is solicited.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

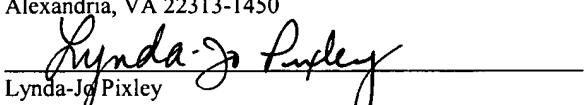
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It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



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CUSTOMER NO. 00826 ALSTON & BIRD LLP Bank of America Plaza 101 South Tryon Street, Suite 4000 Charlotte, NC 28280-4000 Tel Raleigh Office (919) 862-2200 Fax Raleigh Office (919) 862-2260	"Express Mail" mailing label number EV 387068735 US Date of Deposit July 7, 2005 I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450  _____ Lynda-Jo Pixley
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